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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,222	01/09/2001	Dilip Chokshi	1114-2	6305

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HOFFMANN & BARON, LLP  
6900 JERICHO TURNPIKE  
SYOSSET, NY 11791

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/08/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/757,222

Applicant(s)

CHOKSHI, DILIP

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15-57 is/are pending in the application.
- 4a) Of the above claim(s) 15-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's amendment filed December 12, 2002 has been received and entered into the case.

#### ***Claim Objections***

1. Claim 53 is objected to because of the following informalities: Claim 53 depends on itself. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 49 – 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 6, “the ubiquinone” lacks sufficient antecedent basis.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 49 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomita.

Applicant claims a nutritional composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the composition is obtained by fermenting yeast, bacteria or both in the presence of coenzyme Q10; wherein the yeast and bacteria are suitable for mammal consumption and produce the glycoprotein matrix, thereby binding the glycoprotein matrix to the ubiquinone.

Tomita teaches antioxidant compositions comprising lactoferrin hydrosylates (glycoproteins) and coenzyme Q (col.e3 line 35-52). The compositions are disclosed to be effective as health-keeping agents, or nutritional supplements (col.8 line 51-64).

The reference anticipates the claimed subject matter.

6. Claims 49 – 51, 54 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Seuref.

Applicant claims a nutritional composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the composition is obtained by fermenting yeast, bacteria or both in the presence of coenzyme Q10; wherein the yeast and bacteria are suitable for mammal consumption and produce the glycoprotein matrix, thereby binding the glycoprotein matrix to the ubiquinone. The Q10 is present at about 5 – 15%, the ratio of matrix:Q10 is between about 1:1 – 10:1, and the yeast includes *Saccharomyces cerevisiae*.

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Seuref teaches compositions of coenzyme Q10 and brewer's yeast (*S. cerevisiae*) (abstract). Specifically, the yeast is disclosed to contain 40% proteins (or glycoproteins). Compositions comprising 5 – 15% Q10 and ratios between 1:1 – 10:1 are disclosed (p.5 line 10-15).

The reference anticipates the claimed subject matter.

7. Claims 49, 54 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao.

Applicant claims a nutritional composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the composition is obtained by fermenting yeast, bacteria or both in the presence of coenzyme Q10; wherein the yeast and bacteria are suitable for mammal consumption and produce the glycoprotein matrix, thereby binding the glycoprotein matrix to the ubiquinone. The yeast includes *Saccharomyces cerevisiae*.

Nakao teaches compositions of coenzyme Q10 wherein yeasts are fermented to produce coenzyme Q10 (examples, claims). Nakao additionally teaches that ubiquinones are obtainable by incubating bacteria and *S. cerevisiae* (col.1 line 35-48).

The reference anticipates the claimed subject matter.

8. Claims 49, 52 – 53, and 55 – 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Giampapa.

Applicant claims a nutritional composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the composition is obtained by fermenting yeast, bacteria or both in the presence of coenzyme Q10; wherein the yeast and bacteria are suitable for mammal consumption

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and produce the glycoprotein matrix, thereby binding the glycoprotein matrix to the ubiquinone. The composition further comprises a bioflavonoid, hesperidin. The bacteria is *Lactobacillus acidophilus*, *Bacterium bifidus*, or both.

Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10, and lipase (a glycoprotein) (col.8 line 38 – col.10 line 3).

The reference anticipates the claimed subject matter.

Applicant argues that the references do not teach the method by which the Q10 is produced and that the references do not teach the Q10 bound to a glycoprotein matrix.

However, these arguments fail to persuade because although the references above do not teach the method by which the Q10 is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

It is noted that the process of fermenting yeast and/or bacteria in the presence of coenzyme Q10 is commonly practiced as demonstrated by Nakao. Nakao teaches fermenting yeast and/or bacteria to produce coenzyme Q10 that is isolated from the culture medium, which meets the claimed “fermenting yeast, bacteria or both, in the presence of coenzyme Q10”.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 49 – 51, 54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao.

Applicant claims a nutritional composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the composition is obtained by fermenting yeast, bacteria or both in the presence of coenzyme Q10; wherein the yeast and bacteria are suitable for mammal consumption and produce the glycoprotein matrix, thereby binding the glycoprotein matrix to the ubiquinone. The coenzyme is present at about 5 – 15%, the ratio of matrix:Q10 is between about 1:1 – 10:1, and the yeast is *Saccharomyces cerevisiae*.

Nakao teaches compositions of coenzyme Q10 wherein yeasts are fermented to produce coenzyme Q10 (examples, claims). Nakao additionally teaches that ubiquinones are obtainable from bacteria and *S. cerevisiae* (col.1 line 35-48).

Nakao does not teach the compositions with the claimed amounts or ratios of Q10 to glycoprotein. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such volumes and ratios as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in

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the art would have been motivated by routine practice to optimize the amounts of Nakao with a reasonable expectation for successfully obtaining the ubiquinone composition of Nakao.

11. Claims 49 – 53 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa.

Applicant claims a nutritional composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the composition is obtained by fermenting yeast, bacteria or both in the presence of coenzyme Q10; wherein the yeast and bacteria are suitable for mammal consumption and produce the glycoprotein matrix, thereby binding the glycoprotein matrix to the ubiquinone. The coenzyme is present at about 5 – 15%, the ratio of matrix:Q10 is between about 1:1 – 10:1, and the composition further comprises a bioflavonoid hesperidin.

Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10, lipase (a glycoprotein) (col.8 line 38 – col.10 line 3).

Giampapa does not teach the composition comprising 5 – 15% Q10 or the ratio of glycoprotein to Q10 as claimed. However, it would have been obvious to one of ordinary skill in the art to optimize such volumes and ratios since it was routine practice in the art at the time of the claimed invention. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of Giampapa with a reasonable expectation for successfully obtaining a vitamin supplement as disclosed by Giampapa.



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12. Claims 49 – 41 and 55 – 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metz and Kruzel.

Applicant claims a nutritional composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the composition is obtained by fermenting yeast, bacteria or both in the presence of coenzyme Q10; wherein the yeast and bacteria are suitable for mammal consumption and produce the glycoprotein matrix, thereby binding the glycoprotein matrix to the ubiquinone. Specifically the coenzyme Q10 is in an amount of about 5 – 15%, or wherein the ratio of glycoprotein matrix to ubiquinone is between about 1:1 to 10:1. The bacteria is *Lactobacillus*, *Lactobacillus acidophilus* or *Bacterium bifidus*.

Metz teaches a food supplement for aiding the intestines comprising coenzyme Q10 and *Lactobacillus acidophilus* (abstract).

Kruzel teaches nutritional food supplements for preventing microbial infections comprising lactoferrin (a glycoprotein) (abstract).

The references do not teach each of the ingredients together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their common benefit. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

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Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that the references do not teach the method by which the Q10 is produced and that the references do not teach the Q10 bound to a glycoprotein matrix.

However, these arguments fail to persuade because although the references above do not teach the method by which the Q10 is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

It is noted that the process of fermenting yeast and/or bacteria in the presence of coenzyme Q10 is commonly practiced as demonstrated by Nakao. Nakao teaches fermenting yeast and/or bacteria to produce coenzyme Q10 that is isolated from the culture medium, which meets the claimed “fermenting yeast, bacteria or both, in the presence of coenzyme Q10”.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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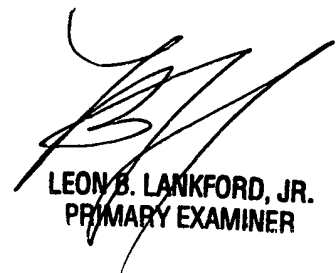
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
April 2, 2003



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER